UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE NEW YORK TIMES COMPANY AND SHEILA KAPLAN, Plaintiffs, -against- U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	:	19-CV-4740 (VEC) OPINION AND ORDER

VALERIE CAPRONI, United States District Judge:

Plaintiffs The New York Times Company and Sheila Kaplan, a reporter for *The New York Times*, have sued the Food and Drug Administration ("FDA") under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Plaintiffs seek disclosure of records JUUL Labs, Inc. ("Juul")[1] submitted to FDA in response to a document request and during an on-site inspection of Juul's headquarters. *See* Compl. ¶¶ 8, 13, Dkt. 1. Animating Plaintiffs' FOIA request is an attempt to gain additional information about the use of Juul products by minors, a growing concern for both FDA and the public at large. Pursuant to a stipulation between the parties, FDA produced close to 2,000 pages of records and several multimedia records; FDA withheld, however, more than 20,000 pages of records and many more records in their entirety. *See* Def. Mem. at 5. For all records withheld or redacted, FDA has invoked FOIA's Exemption 4, which covers "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Plaintiffs and FDA have cross-moved for

[1] The parties alternate between referring to the company as "Juul" and "JUUL." For clarity's sake, the Court refers to the company throughout, including in quotations from the parties' briefing, as "Juul."

summary judgment. For the reasons discussed below, both motions for summary judgment are DENIED.

BACKGROUND[2]

Juul manufactures electronic nicotine delivery system ("ENDS") products that are an alternative to combustible cigarettes. Engelke Decl. ¶ 3. In April 2018, FDA issued a request to Juul under Section 904(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 387d. *Id.* ¶ 6; *see also* Apr. 24, 2018 FDA Letter, Dkt. 23-1. Specifically, FDA requested "documents relating to marketing practices and research on marketing, effects of product design, public health impact, and adverse experiences and complaints related to Juul products." Apr. 24, 2018 FDA Letter at 1. FDA noted its request was animated by "growing concern about the popularity of Juul products among youth" and the "great public health concern" amid "[w]idespread reports of youth use of Juul products." *Id.* at 1–2. Among a wide range of information sought, FDA requested records reflecting "[c]onsumer perception studies/market testing," as well as records related to "[a]dverse experiences and complaints involving youth," such as "consumer complaints related to youth use associated with Juul products." *Id.* at 3–4. Juul produced to FDA documents responsive to its Section 904(b) request in June 2018. Engelke

[2] All facts stated herein are drawn from the Complaint and the parties' declarations submitted in connection with these motions. The facts discussed above are undisputed unless otherwise noted. The Court will refer to the relevant submissions as follows: Defendant's Memorandum of Law in support of its motion for summary judgment, Dkt. 20, as "Def. Mem."; Plaintiffs' Memorandum of Law in support of their cross-motion for summary judgment and in opposition to Defendant's motion for summary judgment, Dkt. 26, as "Pls. Mem."; Defendant's Memorandum of Law in further support of its motion for summary judgment and in opposition to Plaintiffs' cross-motion for summary judgment, Dkt. 32, as "Def. Reply"; Plaintiffs' Reply Memorandum of Law in further support of their cross-motion for summary judgment, Dkt. 34, as "Pls. Reply"; Declaration of Sarah B. Kotler, Dkt. 21, as "Kotler Decl."; Declaration of Maqui Q. Barnes, Dkt. 22, as "Barnes Decl."; Declaration of Joanna Engelke in support of the U.S. Food and Drug Administration's motion for summary judgment, Dkt. 23, as "Engelke Decl."; Supplemental Declaration of Marqui Q. Barnes, Dkt. 33, as "Barnes Suppl. Decl."; Declaration of Alexandra Perloff-Giles, Dkt. 35, as "Perloff-Giles Decl."; *Vaughn* Index for *The New York Times Co. v. FDA*, 19 Civ. 4740 (VEC), Dkt. 22-3, as "*Vaughn* Index"; Amended *Vaughn* Index for *The New York Times Co. v. FDA*, 19 Civ. 4740 (VEC), Dkt. 33-1, as "Am. *Vaughn* Index."

Decl. ¶ 8. Shortly thereafter, in September 2018, FDA conducted an inspection of Juul's headquarters, which lasted several days and covered multiple topics, including "product design, marketing plans, and studies relating to youth prevention." *Id.* ¶ 10. During the inspection, Juul provided FDA inspectors with additional records. *Id.*

On June 25, 2018, Plaintiffs submitted a FOIA request to FDA ("First FOIA Request") seeking "a copy of all materials that are submitted in any form, to the FDA, from Juul or its representatives, lawyers, lobbyists, and other parties, that are responsive to" the April 2018 letter request from FDA to Juul pursuant to Section 904(b). Kotler Decl. ¶ 11; Compl. ¶ 8; *see also* Dkt. 21-1 (June 25, 2018 FOIA request). On October 18, 2018, Plaintiffs submitted a second FOIA request to FDA ("Second FOIA Request") seeking "the marketing and advertising records, and sales strategy records, that the FDA obtained from Juul during its visit to headquarters the last week of September [2018]." Kotler Decl. ¶ 14; Compl. ¶ 13; *see also* Dkt. 21-3 (Oct. 18, 2018 FOIA request).

In November 2018, FDA responded to Plaintiffs' first FOIA request, stating that it had found responsive records but that the records "may contain information that FOIA Exemption 4 prohibits from release as trade secrets and/or confidential commercial information." Compl. ¶ 11; *see also* Barnes Decl. ¶ 19. Also in November 2018, because FDA's September 2018 inspection of Juul remained open, FDA denied Plaintiffs' Second FOIA Request, citing FOIA Exemption 7(A), 5 U.S.C. § 552(b)(7)(A), and related regulations. Compl. ¶ 14; Kotler Decl. ¶ 17. Plaintiffs appealed that decision to the U.S. Department of Health and Human Services ("HHS") in January 2019. Compl. ¶ 15.

On May 22, 2019, having failed to receive any records in response to either of its FOIA requests and not having received a decision on its appeal to HHS, Plaintiffs commenced this

action pursuant to 5 U.S.C. § 552. *See* Compl. ¶ 1. After Plaintiffs filed suit, because FDA's inspection of Juul's headquarters had since closed, FDA reprocessed their Second FOIA Request, mooting Plaintiffs' appeal to HHS. Barnes Decl. ¶ 16; Def. Mem. at 4.

Pursuant to an FDA regulation on public information, 21 C.F.R. § 20.61(e)(1), and Executive Order 12600, FDA sent Juul predisclosure notification letters concerning Plaintiffs' FOIA requests, instructing Juul to review the responsive records and "provide a detailed justification as to whether any of this information is confidential business information that should be withheld pursuant to FOIA Exemption 4." Barnes Decl. ¶¶ 19, 25; Compl. ¶ 11; Nov. 9, 2018 FDA Letter, Dkt. 22-1; *see also* July 16, 2019 FDA Letter, Dkt. 22-2 (requesting that Juul "provide a detailed justification as to whether any of this information falls within Exemption 4"). Juul responded to FDA's letters designating certain records as exempt from disclosure under Exemption 4. Barnes Decl. ¶¶ 21, 25. FDA agreed with all of Juul's designations of material exempt under Exemption 4. *Id.* ¶¶ 22, 26. Although FDA produced to Plaintiffs records that Juul had deemed non-exempt, it withheld the vast majority of records that are responsive to Plaintiffs' FOIA requests. *See id.* ¶¶ 23, 27.

In December 2019, FDA provided to Plaintiffs a one-page document drafted by Juul titled "Index of Document Categories." Perloff-Giles Decl. ¶ 2. The index represents Juul's attempt to group into nine categories the records it classified as protected under Exemption 4 in response to the First FOIA Request and provides brief descriptions of each category of records. *Id.* ¶ 2, Ex. A. After reviewing this index, Plaintiffs informed FDA that, because "[s]ome of those categories of documents seem especially likely to contain documents (and/or segregable portions of documents) that are not properly covered by Exemption 4," they would contest FDA's decision to withhold documents in five of the nine categories: (1) Marketing Strategy

Documents; (2) Product Testing Documents; (3) Consumer Experience Documents; (4) Youth Prevention Documents; and (5) Regulatory Compliance Documents. *Id.* ¶ 3. Plaintiffs subsequently informed the Court of their intention not "to contest the adequacy of the search conducted by [FDA] or FDA's withholdings regarding certain categories of documents under Exemption 4." Dkt. 16 at 1. Plaintiffs made clear, however, that they intended to "contest the withholding in full" as to the five categories of documents listed above. *Id.* at 1–2.

On March 3, 2020, FDA filed its motion for summary judgment. *See* Notice of Mot., Dkt. 19. FDA submitted a *Vaughn* index with its motion, which identified each record withheld by "Record Category" and included a column for "Description of Record." *See Vaughn* Index. The "Record Category" column reflects Juul's categorization of the documents responsive to Plaintiffs' First FOIA Request and FDA's good-faith efforts to place the records responsive to Plaintiffs' Second FOIA Request into those same categories.[3] Barnes Decl. ¶ 28. FDA independently drafted the brief information in the "Description of Record" column for all records, using its best efforts to describe "the nature of the record after reviewing it on its face." *Id.* ¶¶ 28–29.

On March 24, 2020, after FDA had filed its motion but before Plaintiffs had filed their cross-motion, the parties jointly informed the Court that they had narrowed the scope of the case even further; after reviewing FDA's *Vaughn* index, Plaintiffs "agreed to limit the case to certain documents tagged in the *Vaughn* index as 'Consumer Experience' documents responsive to [the First FOIA Request]." Dkt. 24 at 1. Thus, Plaintiffs agreed not to contest FDA's decision to withhold records from the other four categories of documents that they had initially identified and also agreed not to contest FDA's decision to withhold records responsive to Plaintiffs'

[3] For reasons that are unclear, Juul did not categorize the documents FDA obtained as part of its inspection of Juul's headquarters. *See* Barnes Decl. ¶ 28.

Second FOIA Request. On March 31, 2020, Plaintiffs filed their cross-motion for summary judgment. *See* Notice of Mot., Dkt. 25. In their motion, Plaintiffs identified six sets of documents within the "Consumer Experience" category of which they sought disclosure: (1) a consumer outreach study; (2) presentations regarding consumer survey results; (3) presentations regarding consumer segmentation; (4) presentations regarding parent focus group results; (5) consumer product complaint summary reports; and (6) email correspondence between Juul and consumers regarding complaints about Juul and its products. Pls. Mem. at 7.

In response, along with its reply memorandum, FDA submitted an amended *Vaughn* index, which included only those records still sought by Plaintiffs. Barnes Suppl. Decl. ¶¶ 4–5; Am. *Vaughn* Index. In addition to culling the documents included in the original *Vaughn* index, FDA also changed the categorization of the first four sets of documents still sought by Plaintiffs from Consumer Experience to Consumer Research and Strategy, a category from which Plaintiffs had agreed ahead of the parties' summary judgment motions it would not seek any documents. Barnes Suppl. Decl. ¶ 8. FDA contends that it had mistakenly included those documents in the original *Vaughn* index and had compounded its mistake by labeling them as Consumer Experience. *See* Def. Reply at 3–5. In the amended *Vaughn* index, FDA, based on what it describes as a "re-review" of all of the records Plaintiffs still seek, also made some additional corrections and provided supplemental information on certain documents. *See* Barnes Suppl. Decl. ¶¶ 4, 8, 11. Whereas FDA had accepted Juul's categorization without question in drafting the original *Vaughn* index, in the amended *Vaughn* index, FDA noted that it had some minor disagreements with Juul's categorizations but nevertheless retained the categorizations provided by Juul. *See id.* ¶¶ 8, 12.

DISCUSSION

I. Legal Standard Under FOIA

Under FOIA, agency records must be disclosed unless they fall within one of FOIA's enumerated exemptions. *See Tigue v. U.S. Dep't of Just.*, 312 F.3d 70, 76 (2d Cir. 2002) (quoting *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 7 (2001)). The Second Circuit has made clear that FOIA is to be "construed broadly to provide information to the public in accordance with its purposes" — "promot[ing] honest and open government" and "assur[ing] the existence of an informed citizenry to hold the governors accountable to the governed." *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 478 (2d Cir. 1999) (cleaned up). As such, FOIA's exemptions must be "construed narrowly." *Id.* (quoting *Ethyl Corp. v. U.S. Env't Prot. Agency*, 25 F.3d 1241, 1245 (4th Cir. 1994)); *see also Ctr. for Const. Rts. v. Cent. Intel. Agency*, 765 F.3d 161, 166 (2d Cir. 2014) ("Exceptions to FOIA's general principle of broad disclosure of Government records . . . have consistently been given a narrow compass." (cleaned up)). Nevertheless, FOIA's exemptions reflect Congress's recognition that there must be "a workable balance between the right of the public to know and the need of the Government to keep information in confidence." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 152 (1989) (citation omitted); *see also Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) ("FOIA expressly recognizes that important interests are served by its exemptions, and those exemptions are as much a part of FOIA's purposes and policies as the statute's disclosure requirement." (cleaned up)). "The government bears the burden of demonstrating that an exemption applies to each item of information it seeks to withhold, and all doubts as to the applicability of the exemption must be resolved in favor of disclosure." *Florez v. Cent. Intel. Agency*, 829 F.3d 178, 182 (2d Cir. 2016) (quoting *Ctr. for Const. Rights*, 765 F.3d at 166).

Even where an agency's records fall within an enumerated exemption, the agency still must produce any non-exempt portions of the record that are "reasonably segregable" from the exempt portions of the record. *See* 5 U.S.C. § 552(b).

Given the rarity of factual disputes in FOIA cases, summary judgment is the most common procedural vehicle by which FOIA cases are resolved. *See, e.g.*, *Kaye v. U.S. Dep't of Homeland Sec.*, No. 16-CV-9384, 2018 WL 456303, at *1 (S.D.N.Y. Jan. 17, 2018). Summary judgment is appropriate if a moving party "shows that there is no genuine dispute as to any material fact and [it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "A district court in a FOIA case may grant summary judgment in favor of an agency 'on the basis of agency affidavits if they contain reasonable specificity of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith.'" *Grand Cent. P'ship*, 166 F.3d at 478 (quoting *Gallant v. Nat'l Lab. Rels. Bd.*, 26 F.3d 168, 171 (D.C. Cir. 1994)). District courts accord agencies' affidavits in support of their decisions to withhold records "a presumption of good faith," and "the agency's justification is sufficient if it appears logical and plausible." *Seife v. Food & Drug Admin.*, No. 17-CV-3960, 2020 WL 5913525, at *3 (S.D.N.Y. Oct. 6, 2020) (cleaned up). "Summary judgment in favor of the FOIA plaintiff is appropriate when an agency seeks to protect material which, even on the agency's version of the facts, falls outside the proffered exemption." *Nat. Res. Def. Council, Inc. v. U.S. Dep't of Interior*, 36 F. Supp. 3d 384, 398 (S.D.N.Y. 2014) (cleaned up).

Under FOIA, a district court must assess an agency's decision to withhold records *de novo* and "may examine the contents of . . . agency records *in camera* to determine whether such records or any part thereof shall be withheld under any of the exemptions." 5 U.S.C. §

552(a)(4)(B). Despite its availability under FOIA, "[a] district court should not undertake *in camera* review of withheld documents as a substitute for requiring an agency's explanation of its claimed exemptions in accordance with *Vaughn* [*v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973)]." *Seife v. U.S. Dep't of State*, 298 F. Supp. 3d 592, 630 (S.D.N.Y. 2018) (quoting *Spirko v. U.S. Postal Serv.*, 147 F.3d 992, 997 (D.C. Cir. 1998)). Accordingly, *in camera* review is treated as "the exception, not the rule" in adjudicating FOIA actions. *Loc. 3, Int'l Brotherhood of Elec. Workers, AFL-CIO v. Nat'l Lab. Rels. Bd.*, 845 F.2d 1177, 1180 (2d Cir. 1988); *see also Halpern v. Fed. Bureau of Investigation.*, 181 F.3d 279, 292 (2d Cir. 1999) (noting that the Second Circuit has "adopted a restrained approach permitting [*in camera*] review where the record show[s] the reasons for withholding were vague or where the claims to withhold were too sweeping or suggestive of bad faith, or where it might be possible that the agency had exempted whole documents simply because there was some exempt material in them"). Thus, "[t]he district court should first offer the agency the opportunity to demonstrate, through detailed affidavits and oral testimony, that the withheld information is clearly exempt and contains no segregable, nonexempt portions." *Seife*, 298 F. Supp. 3d at 630 (citation omitted).

II. FDA Waived Plaintiffs' Waiver of Access to the Consumer Research and Strategy Documents

Before assessing the adequacy of the parties' respective arguments in support of their cross-motions for summary judgment, the Court must first address a threshold issue concerning the categorization of records in FDA's original *Vaughn* index and Plaintiffs' agreement not to seek disclosure of certain categories of documents. As described above, FDA relied on Juul's categorization of records in Juul's predisclosure notification responses in order to group records into one of nine categories; Juul's categorization is reflected in the "Record Category" column in FDA's original and amended *Vaughn* indices. *See Vaughn* Index; Am. *Vaughn* Index. Based on

Juul's description of each category of documents, Plaintiffs elected to contest FDA's decision to withhold records in five of nine categories; Plaintiffs elected *not* to contest FDA's decision to withhold records in the "Consumer Research and Strategy" category. *See* Perloff-Giles Decl. ¶¶ 2–3, Ex. A.

According to FDA, its original *Vaughn* index contained only records that fell into the five categories of documents as to which Plaintiffs continued to seek disclosure. *See* Def. Mem. at 5–7; *Vaughn* Index. As such, the *Vaughn* index was limited to those records "that remain[ed] at issue" in this action. Def. Mem. at 7. In reliance on FDA's *Vaughn* index, in cross-moving for summary judgment, Plaintiffs agreed to further limit its motion to six sets of documents that had been categorized as "Consumer Experience" records. *See* Pls. Mem. at 7. Plaintiffs argued specifically for disclosure of each set of documents, believing them to fall within the Consumer Experience category.

Much to Plaintiffs' surprise, however, in opposing Plaintiffs' cross-motion and responding in further support of its motion for summary judgment, FDA disclosed that it had erred in compiling the original *Vaughn* index. While FDA had included the first four sets of documents that Plaintiffs continued to seek in its original *Vaughn* index and had categorized them as Consumer Experience documents, in reality, they should not have been included in the original *Vaughn* index at all, because Juul, on whose categorizations FDA relied, had labeled them as Consumer Research and Strategy documents.[4] FDA's mistake was thus twofold: It erroneously included documents in the original *Vaughn* index that Plaintiffs had agreed not to

[4] The four sets of documents are: (1) a consumer outreach study; (2) presentations regarding consumer survey results; (3) presentations regarding consumer segmentation; and (4) presentations regarding parent focus group results. *See* Def. Reply at 4; Barnes Suppl. Decl. ¶¶ 5, 8; Am. *Vaughn* Index at 1–8. FDA also amended the descriptions of certain records described as presentations regarding "consumer survey results," noting that they are better described as presentations relating to either "retail survey results," "consumer survey proposals," "consumer segmentation," or "consumer research." Barnes Suppl. Decl. ¶ 8.

pursue, and it mislabeled the erroneously-included documents as falling within the "Consumer Experience" category when, *as categorized by Juul*, they should have been categorized as "Consumer Research and Strategy" records. Consistent with its procedure for compiling the original *Vaughn* index, FDA again relied on Juul's categorization of the documents in question by labeling them as Consumer Research and Strategy documents in the amended *Vaughn* index.[5] *See* Am. *Vaughn* Index at 1–8.

FDA now argues that, notwithstanding its mistake, Plaintiffs are bound by their initial stipulation from January 2020, in which they agreed not to seek judicial relief for any documents falling within the Consumer Research and Strategy category. *See* Def. Reply at 5–7. FDA thus contends that Plaintiffs have waived their right to challenge FDA's withholding of these four sets of documents. *Id.* Plaintiffs predictably contest FDA's attempt to punish them for its own mistake. Plaintiffs first argue that, by amending its document descriptions and noting its disagreement with Juul's categorization of certain documents when it created the amended *Vaughn* index, FDA has made clear that Juul's categories of responsive documents are fluid and open to interpretation; the Court should thus find that Plaintiffs did not waive their right to seek these four sets of documents, notwithstanding Juul's categorization of them as Consumer Research and Strategy records. *See* Pls. Reply at 1–4. Plaintiffs further argue that, even if the Court finds that they waived their right to contest FDA's decision to withhold these documents,

[5] FDA agrees with Juul's categorization of the four sets of records as being Consumer Research and Strategy records, with the exception of records "that appear to relate to retailers or youth use (rather than consumers)." Barnes Suppl. Decl. ¶ 8. FDA's ready willingness to accept Juul's categorization of documents in compiling the original *Vaughn* index as compared to its more discerning "re-review" of the records in compiling the amended *Vaughn* index raises, at minimum, concern about the thoroughness of FDA's initial review of these records. While the Court has no reason to believe that any discrepancies are a result of bad faith, this vacillation by FDA at least supports the Court's conclusion, discussed below, that the existing *Vaughn* index is wholly inadequate to support FDA's motion for summary judgment.

FDA waived its right to enforce Plaintiffs' waiver when it addressed the unpreserved claim on the merits rather than arguing waiver. *See id.* at 4–5.

At the outset, the Court agrees with FDA that Plaintiffs waived the right to challenge FDA's decision to withhold these four sets of documents, notwithstanding its mistaken inclusion of the documents in the original *Vaughn* index. Plaintiffs opted to contest FDA's decision to withhold only five categories of documents and communicated that decision to the Court by way of stipulation in January 2020, *before* FDA had produced a *Vaughn* index and before Plaintiffs had access to any specific record descriptions. Thus, at the time Plaintiffs agreed not to seek disclosure of Consumer Research and Strategy documents, Plaintiffs had no knowledge of any specific documents within that category beyond Juul's one-sentence description.[6] Plaintiffs cannot now argue that they did not intentionally relinquish their right to contest the FDA's decision to withhold the four sets of documents just because they learned more about those documents when FDA filed its *Vaughn* index. Plaintiffs were under no obligation unilaterally to narrow the scope of their objections to FDA's withholdings based only on the minimal descriptions provided by Juul. By agreeing not to seek entire categories of records before knowing more about the specific records included within each category, Plaintiffs knowingly and voluntarily risked foregoing their opportunity to challenge FDA's decision to withhold specific records that fell into those categories, as determined by Juul.

Plaintiffs, then, are bound by their own assessment of which categories were "especially likely to contain documents (and/or segregable portions of documents) that are not properly covered by Exemption 4." Perloff-Giles Decl. ¶ 3. Assuming the veracity of FDA's affidavits,

[6] Juul's description for the Consumer Research and Strategy category provides: "These documents reflect [Juul]'s internal research into consumer impressions regarding electronic nicotine delivery systems (ENDS) products, including those produced by [Juul] and by competitors." Perloff-Giles Decl. at Ex. A.

FDA did not simply decide to recategorize these records in response to Plaintiffs' selection of records they would pursue; FDA admittedly erred in producing the original *Vaughn* index, including and mislabeling documents that Plaintiffs had already agreed not to pursue. FDA corrected its error and assigned the documents their proper category *as determined by Juul*. Plaintiffs will not now be heard to complain, after seeing what they passed on, that their agreement was not knowing or willing. Buyers' remorse is insufficient to undo the effects of Plaintiffs' valid stipulation.

That analysis notwithstanding, the Court agrees with Plaintiffs that FDA has waived Plaintiffs' waiver of their right to challenge its decision to withhold the four sets of documents at issue. When one party opts to address an issue on the merits rather than assert a procedural argument that its opponent waived a claim or argument, that party can be deemed to have "waived the waiver." *See, e.g.*, *United States v. Macias*, 789 F.3d 1011, 1024 (9th Cir. 2015) (Wardlaw, J. concurring in part and dissenting in part) ("Where the government elects to address an unpreserved claim on the merits rather than to argue that the defendant waived the claim by failing to object on that basis in the trial court, it is deemed to waive the waiver."); *Westefer v. Snyder*, 422 F.3d 570, 584 n.20 (7th Cir. 2005) (finding that by focusing "solely on the adequacy of the [plaintiffs'] brief" and not arguing that plaintiffs' waived their contention, defendants "waived any waiver argument on this issue" because the court must "hold fast to the principle that a defense of waiver may itself be waived if not raised"); *United States v. Doe*, 239 F.3d 473, 475 (2d Cir. 2001) (opting to address merits of appellant's appeal because government failed to argue his waiver, therefore abandoning its waiver argument); *United States v. Quiroz*, 22 F.3d 489, 490–91 (2d Cir. 1994) (endorsing principle that where the government has failed to argue a defendant's waiver on appeal, the government is deemed to have "waived waiver"); *N.B. v.*

N.Y.C. Dep't of Educ., No. 15-CV-4948, 2016 WL 5816925, at *4 (S.D.N.Y. Sept. 29, 2016) (opting to hear merits of plaintiffs' claims because defendant "chose not to raise a waiver argument, instead engaging with the merits of the . . . issue").

In its opening brief, FDA argued largely in broad strokes, asserting that the five categories of records that Plaintiffs continued to pursue fall within Exemption 4. FDA did, however, explicitly mention "records relating to consumer surveys and draft letters to consumers" and "videos of focus groups, interviews, and sensory groups" as two of the types of records that, as reflected in the original *Vaughn* Index, Plaintiffs were still pursuing and FDA was still seeking to withhold. Def. Mem. at 7. These are precisely the records that, in producing the amended *Vaughn* index, FDA has relabeled as Consumer Research and Strategy records. *See, e.g.*, Vaughn Index at 18 (record with Bates range JUULLabs_00030229-JUULLabs_00030310, described as "Presentation regarding consumer survey results," categorized as "Consumer Experience" document); Am. *Vaughn* Index at 1 (categorizing same record as "Consumer Research and Strategy"). Further, in its opening brief, FDA argued on the merits against disclosure of *all* documents in the original *Vaughn* index, including the Consumer Research and Strategy records that had been mistakenly included. *See* Def. Mem. at 5 (noting that the *Vaughn* index reflected the "4,420 records [that] remain[ed] in dispute"). Accordingly, the Court finds that by supporting on the merits its decision to withhold the four sets of records at issue, FDA waived Plaintiffs' waiver.

Unfortunately, however, the Court does not believe that there is an adequate basis on which to rule on summary judgment as to these four sets of documents; FDA addressed them in a cursory fashion in its opening memorandum and not at all on the merits in its reply. The FDA's description of the documents in the amended *Vaughn* index is similarly sparse. The Court thus

grants FDA's request for an opportunity to submit "further evidence" concerning these four sets of documents. In addition to enhancements to the *Vaughn* index necessitated by the Court's holdings below, FDA must also provide more detail on these four sets of records to the extent it still seeks to withhold them under Exemption 4. Similarly, because the Court is unable to determine on FDA's description of the records that they plainly fall outside the scope of Exemption 4, the Court must deny Plaintiffs' cross-motion for summary judgment as to these records.

III. FDA's Decision to Withhold Records Documenting Complaints Is Overbroad

Two sets of records remain at issue: (1) "consumer product complaint summary reports," and (2) "other records reflecting communications between Juul and third parties, as well as internal Juul analysis and communications." Def. Reply at 7. FDA has provided minimal, if any, detail on these records beyond the bare minimum necessary to provide Plaintiffs and the Court with some vague, general sense of their content. After "re-review[ing]" these records in response to Plaintiffs' cross-motion for summary judgment, however, FDA did provide some additional detail, although still sparse and largely unhelpful in permitting the Court to engage in a meaningful analysis of whether these records fall within the scope of Exemption 4. *See id.* at 5.

Specifically, FDA states that the consumer product complaint summary reports can be generally categorized into five sub-categories: (1) customer complaints about the physical characteristics of a Juul product; (2) customer complaints about the effects of a Juul product; (3) *non*-customer complaints about the effects of a Juul product; (4) *non*-customer complaints about the distribution of Juul's products; and (5) *non*-customer complaints about retailers of Juul's

products.[7] Barnes Suppl. Decl. ¶ 9. FDA further notes that the complaints contained within the summary reports document multiple forms of communication between Juul and third parties, including "emails, phone calls, 'chats,' and submissions via a Juul 'support form.'" *Id.* ¶ 10. FDA also clarifies that, to the extent there was any confusion, the complaint summary reports "generally contain Juul's analysis, in addition to communications with third parties." *Id.* ¶ 8; *see also, e.g.*, Am. *Vaughn* Index at 9 (describing consumer product complaint summary reports as "including complainant communication to Juul, Juul's analysis regarding the complaint, and any response by Juul to complainant"). Finally, FDA states that documents that had been described as "[e]mails from consumer to Juul regarding product complaints" in the original *Vaughn* index actually "reflect email communications from *non-customers* to Juul about Juul product distribution, including potential youth use." Barnes Suppl. Decl. ¶ 11 (emphasis added). These records too, FDA asserts, "include Juul's classification and evaluation of the complaint and, in certain instances, internal Juul emails regarding the complaint." *Id.*

FDA argues that all of the records it has withheld are protected from disclosure by FOIA Exemption 4, which "shields from mandatory disclosure '[trade secrets and] commercial or financial information obtained from a person and [that is] privileged and confidential.'" *Argus Leader*, 139 S. Ct. at 2362 (quoting 5 U.S.C. § 552(b)(4)). "Exemption Four applies if a tripartite test is satisfied: (1) The information for which exemption is sought must be a trade secret or commercial or financial in character; (2) it must be obtained from a person; and (3) it must be privileged or confidential." *Nadler v. Fed. Deposit Ins. Corp.*, 92 F.3d 93, 95 (2d Cir. 1996) (cleaned up). Because the parties do not dispute that Juul qualifies as a "person" as

[7] As discussed above, FDA also notes its disagreement with the classification of *non*-customer complaints as "Consumer Experience" records, but because it had already agreed to maintain the categorizations based on Juul's original assignments, FDA retained that description in the amended *Vaughn* index. *Id.* ¶ 12; *see also* Am. *Vaughn* Index at 1 n.1.

defined by FOIA,[8] at issue is whether the information in the records is (a) commercial and (b) confidential.

A. Commercial or Financial Information

To fall within Exemption 4, the "information itself must in some fashion be commercial or financial in nature or use." *N.Y. Pub. Int. Rsch. Grp. v. Env't Prot. Agency*, 249 F. Supp. 2d 327, 333 (S.D.N.Y. 2003). The Second Circuit has been far from precise in defining the term "commercial," deeming it to encompass information "pertaining or relating to or dealing with commerce." *Am. Airlines, Inc. v. Nat'l Mediation Bd.*, 588 F.2d 863, 870 (2d Cir. 1978). As a general rule, courts typically find records to be commercial if they "reveal basic commercial operations, such as sales statistics, profits and losses, and inventories, or relate to the income-producing aspects of a business." *Plumbers & Gasfitters Loc. Union No. 1 v. U.S. Dep't of Interior*, No. 10-CV-4882, 2011 WL 5117577, at *2 (E.D.N.Y. Oct. 26, 2011) (citation omitted).

The parties dispute the proper scope of the "commercial information" prong of Exemption 4, with the disagreement centering on the way in which the Second Circuit and the D.C. Circuit have (or have not) differed in interpreting this exemption. The D.C. Circuit admittedly has adopted a "more expansive reading of Exemption 4," *see 100Reporters LLC v. U.S. Dep't of Just.*, 316 F. Supp. 3d 124, 141 (D.D.C. 2018), which may conflict with the Second Circuit's practice of affording FOIA's exemptions "a narrow compass," *see Inner City Press/Cmty. on the Move v. Bd. of Governors of Fed. Rsrv. Sys.*, 463 F.3d 239, 244 (2d Cir. 2006) (quoting *U.S. Dep't of Just. v. Tax Analysts*, 492 U.S. 136, 151 (1989)). Specifically, courts within the D.C. Circuit find Exemption 4 to "reach[] more broadly and appl[y] (among

[8] *See* 5 U.S.C. § 551(2) ("'[P]erson' includes an individual, partnership, corporation, association, or public or private organization other than an agency.").

other situations) when the provider of the information has a commercial interest in the information submitted to the agency." *Baker v. Hostetler LLP v. U.S. Dep't of Com.*, 473 F.3d 312, 319 (D.C. Cir. 2006). In facing this precise issue — also involving The New York Times — a sister court recently found that, while perhaps unclear whether the Second Circuit has embraced the D.C. Circuit's "commercial interest" standard, "courts in this Circuit have noted that Exemption 4 includes at least information that has 'intrinsic commercial value,' the disclosure of which would 'jeopardize [a commercial entity's] commercial interests or reveal information about [its] ongoing operations.'" *N.Y. Times Co. v. U.S. Dep't of Just.*, No. 19-CV-1424, 2021 WL 371784, at *10 (S.D.N.Y. Feb. 3, 2021) (quoting *N.Y. Pub. Int. Rsch. Grp.*, 249 F. Supp. 2d at 334).

Ultimately, as in *N.Y. Times Co.*, the Court need not determine whether the Second Circuit has or would embrace the D.C. Circuit's "commercial interest" standard because FDA has failed to demonstrate the commercial nature of these records. Neither customer nor non-customer complaints are properly classified as commercial information under Exemption 4, at least as described in this case. Juul's internal classifications and analysis of these complaints *may*, however, be appropriately described as commercial and therefore entitled to protection under Exemption 4. Because FDA has failed to provide sufficient details on the nature of any internal Juul communications or analysis, the Court cannot make a reasoned determination that this information qualifies as commercial. FDA has also failed entirely to address whether Juul's internal analysis can be segregated from the complaints themselves. For those reasons, FDA's motion for summary judgment must be denied.

1. Customer and Non-Customer Complaints

In arguing that *customer* complaints were properly withheld under Exemption 4, FDA frames these records generally as documenting a company's interactions with its customers, such

that they undoubtedly relate to commerce. *See* Def. Mem. at 10–11. In support of its position, FDA points to the declaration of Juul's corporate executive, which asserts that documents within the Consumer Experience category writ large reflect Juul's "ongoing commercial strategy for Juul products, as well as the Company's internal strategy and response to consumer complaints." Engelke Decl. ¶ 18. FDA argues that these documents have clear commercial value, disclosure of which would jeopardize Juul's commercial interest and reveal information about Juul's ongoing operations. *See id.*; Def. Reply at 7–8.

With respect to *non*-customer complaints, FDA adopts an even broader argument: Even though these complaints come from people who are not customers and at least some pertain to use of Juul products by underage users, they are "related to commerce and deal with the commercial life of the country." Def. Reply at 9 (quoting *Am. Airlines*, 588 F.2d at 870). FDA asserts that Juul operates in a hypercompetitive environment such that disclosure of any information that touches on Juul's distribution channels or the operation of its products has the potential to reveal information that would be valuable to Juul's competitors and that could damage Juul's competitive standing. *Id.* at 9–10. Therefore, FDA argues, non-customer complaints that pertain, however vaguely, to distribution of Juul products or to Juul retailers must be commercial. *Id.*

In asserting that customer complaints are commercial information, FDA relies exclusively on *Public Citizen v. U.S. Department of Health & Human Services*, 66 F. Supp. 3d 196 (D.D.C. 2014), a case involving the government's withholding of annual reports submitted by pharmaceutical companies to HHS. In *Public Citizen*, the specific records at issue were "disclosure log summaries," which, among other things, "identify and describe interactions with prescribers, consumers, and other customers of [the pharmaceutical company's] various

healthcare products, all vital business functions for [the company]." *Id.* at 208. Importantly, the summaries contained "details of identification and techniques related to [the company's] product promotion, its Code of Business Ethics, and compliance with industry guidelines in general." *Id.* Another company's Disclosure Log Summaries included information "about how [the company] compensates and disciplines its employees, details about internal investigations of the matters reported, . . . along with activities such as promotional statements, call planning activities, sample distribution, travel and expense, and other interactions between sales representatives (or other [company] employees) and doctors, health care providers, and customers." *Id.* (cleaned up). The D.C. district court deemed the disclosure log summaries commercial because the information contained within them was "sufficiently 'instrumental' to the companies' operations to qualify as 'commercial,'" given the "information about interactions between the companies' salespeople and customers, how the companies promote their products, and the way the companies implement their compliance programs." *Id.*

This Court does not read *Public Citizen* to stand for the extremely broad proposition suggested by FDA that *any* interaction between a company and its customers is necessarily commercial information.[9] *See* Def. Mem. at 11; Def. Reply at 8. FDA's initial mistake is failing to distinguish among the different types of interactions a company may have with its customers. A company in the business of selling products obviously has a more significant commercial stake

[9] In the recent *N.Y. Times* case in this district, Judge Failla had occasion to interpret *Public Citizen* in the context of deciding whether documents describing a company's compliance program were commercial. *See N.Y. Times*, 2021 WL 371784, at *10. Judge Failla understood *Public Citizen* to hold that documents describing a company's compliance program can qualify as commercial when combined with other information that can more closely be described as having some intrinsic commercial value, such as "'information about interactions between the companies' salespeople and customers,' or 'how the companies promote their products.'" *Id.* at *10–12 (quoting *Pub. Citizen*, 66 F. Supp. 3d at 208). This Court does not interpret *N.Y. Times* to hold that records reflecting interactions between companies' salespeople and customers are *per se* commercial, but even if it did, that would not change the Court's analysis, as the records at issue here are qualitatively different from documented interactions between a salesperson and a customer.

in interactions between a salesperson seeking to consummate a sale and a customer than it does in other non-sales-related interactions with customers. That is because, as the *Public Citizen* court held, interactions between salespeople and customers are likely to reveal a company's internal operations, including its sales strategies and promotional techniques, and such interactions pertain directly to the company's income-producing activities. *Pub. Citizen*, 66 F. Supp. 3d at 208. It is not the bare interaction between a company and its customer that makes the interaction commercial; the interaction is commercial because of what it reveals about the company's internal operations or income-producing activities. Similarly, a customer-facing sales pitch will necessarily entail a company representative disclosing some information about the company or its products to customers. The same cannot be said for one-sided interactions in which a customer submits a complaint about a company's product or its distribution *to the company*. Such a complaint, without more, does not threaten to reveal anything about a company's internal operations and is meaningfully different than a sales meeting between a salesperson and customer. To hold that *any* interaction between a company and its customers is necessarily commercial would plainly violate the Second Circuit's mandate to construe narrowly FOIA's exemptions.[10] *See Cook v. Nat'l Archives & Recs. Admin.*, 758 F.3d 168, 173 (2d Cir. 2014) ("Because FOIA manifests a strong presumption in favor of disclosure, we construe FOIA exemptions narrowly, resolving doubts in favor of disclosure and imposing on the government the burden of showing that an asserted exemption indeed applies." (cleaned up)); *see also N.Y*

[10] While not presently binding on FDA, it is at least interesting to note that FDA itself has not always considered consumer complaint summaries to be commercial information within the meaning of Exemption 4. Among the records at issue in *Teich v. Food & Drug Administration*, 751 F. Supp. 243, 245 (D.D.C. 1990), was "a summary of consumer complaints about Dow Corning's breast implants." In *Teich*, the company intervened to protect the complaint summary from disclosure under Exemption 4 because FDA had concluded that "Dow Corning's complaint summary would be subject to mandatory disclosure." *Id.* at 246. The court did not have occasion to determine whether the complaint summary was protected under Exemption 4 because "FDA had originally determined that the document could not be shielded under the requirements of that exemption." *Id.* at 249 n.6.

Times, 2021 WL 371784, at *8 ("[N]ot every bit of information submitted to the government by a commercial entity qualifies for protection under Exemption 4." (quoting *Pub. Citizen Health Rsch. Grp. v. Food & Drug Admin.*, 704 F.2d 1280, 1290 (D.C. Cir. 1983)).

Ultimately, the Court does not believe that this case is analogous to *Public Citizen*, and, based on the descriptions provided by FDA, there is nothing about the customer complaints that suggests that they are commercial information within the scope of Exemption 4. Customer complaints to Juul about its products' physical characteristics, viewable to all sighted individuals, or its products' effects, potentially experienced by all users, are qualitatively different from interactions between salespeople and customers. Further, unsolicited customer complaints submitted to Juul are even more distinct from the quintessential examples of commercial information in this circuit, such as sales statistics or inventories, and do not threaten to reveal anything about Juul's internal operations. Juul's conclusory assertion that customer complaints reflect "ongoing commercial strategy" does nothing to change the Court's analysis. *See, e.g.*, *Grand Cent. P'ship*, 166 F.3d at 478 (instructing district courts to award summary judgment to an agency only where affidavits "contain *reasonable specificity* of detail rather than merely conclusory statements" (citation omitted)).[11]

Non-customer complaints are even farther from that which has been classified as commercial under Exemption 4. FDA provided no information about the source of these complaints, disclosing only that they pertain to the effects, distribution, and retailers of Juul's products. Def. Reply at 5. Given FDA's initial request to Juul, however, and FDA's admission

[11] The Court's holding is bolstered by a review of FDA's April 2018 letter to Juul requesting the very records at issue on these motions. *See* Apr. 24, 2018 FDA Letter. In describing the documents FDA sought from Juul, FDA's only request for "consumer complaints" was for "consumer complaints related to youth use associated with Juul products." *Id.* at 4. The Court has little difficulty concluding that consumer complaints about use of Juul products by youths are not commercial information.

that at least some of these non-customer complaints relate to use of Juul products by youths, it seems safe to assume that these complaints derive from parents, concerned citizens, and the like. The Court finds laughable Juul's assertion that non-customer complaints about Juul's distribution and retailers threaten to reveal confidential commercial information about the operation of Juul's devices and the company's distribution channels. *See* Engelke Decl. ¶ 32. These complaints reflect *outsiders'* — and not even Juul customers' — views of Juul's products, their distribution, and retailers that sell Juul products. It is absurd to contend that these non-customer complaints contain intrinsically valuable commercial information that threatens to reveal something about Juul's internal operations or provide Juul's competitors with sensitive information about Juul that can be used to their advantage. To find otherwise based only on FDA's assertion that these complaints "pertain to or are related to commerce and deal with the commercial life of the country" would endorse a view of FOIA's Exemption 4 that is essentially boundless – it would permit the Government to withhold any information a company would prefer not make its way into the public. The Court is disinclined to adopt such an interpretation of FOIA.

In short, customer complaints about the physical characteristics or effects of Juul's products and non-customer complaints about the effects of Juul's products, Juul product distribution, and retailers of Juul products are not exempt from disclosure under FOIA Exemption 4.[12]

[12] The Court refrains from addressing whether Juul's responses to either customers or non-customers can be classified as commercial under Exemption 4 because, as discussed below, this information does not qualify as confidential under Exemption 4's third prong. The Court notes, however, that were it to consider the issue, it would be inclined to classify Juul's responses much the same as complaints submitted to Juul. The likelihood of a company revealing anything of value in responding to a customer or non-customer complaint is almost non-existent. It defies both common sense and sound business practice for a company to disclose information with any intrinsic value in response to, for example, a customer complaining about a product's appearance, or a non-customer complaining about a store's sale of Juul products to underage customers.

2. Internal Juul Communication and Analysis

Although FDA's original *Vaughn* index gave minimal indication whether the complaint summary reports and other records reflecting communications with third parties contained any internal Juul analysis and communications, FDA has now made clear that, for at least some of these records, they do. *See* Def. Reply at 10; Barnes Suppl. Decl. ¶¶ 8, 11. That does not mean, however, that FDA has provided Plaintiffs or this Court with sufficient detail describing the content of the internal Juul analysis or communication. In fact, the amended *Vaughn* index provides no meaningful detail: For each consumer product complaint summary report, FDA states only that it includes "complainant communication to Juul, Juul's analysis regarding the complaint, and any response by Juul to complainant." *E.g.*, Am. *Vaughn* Index at 9. Similarly, for the other records that reflect communications with third parties, FDA notes only that the record reflects "Juul's classification and evaluation of complaint, emails from complainant to Juul, any email response by Juul to complainant, and any internal Juul emails regarding the complaint." *E.g., id.* at 499. The supplemental Barnes Declaration adds nothing beyond that which appears in the amended *Vaughn* index. *See, e.g.*, Barnes Suppl. Decl. ¶ 11.

A *Vaughn* index is intended to "correct the adversarial imbalance of information, and to permit more effective factual review." *Halpern*, 181 F.3d at 290. As such, an essential requirement of a satisfactory *Vaughn* index is that it "include 'a relatively detailed analysis [of the withheld material] in manageable segments' without resort to 'conclusory and generalized allegations of exemptions.'" *Id.* (quoting *Vaughn*, 484 F.2d at 826). When an agency provides a *Vaughn* index characterized by conclusory statements and devoid of fact-specific justifications, plaintiffs are unable "to contest the affidavit in adversarial fashion," the reviewing court is unable "to engage in effective *de novo* review of the [agency's] redactions," and the court is instead given "no other option than to defer to the government's decision to [withhold the

information], unless [the court] conduct[s] a lengthy *in camera* review of the documents, which, of course, defeats the purpose of a *Vaughn* affidavit." *Id.* at 293. "What a district court needs from the government, in a *Vaughn* affidavit, is information that is not only specific enough to obviate the need for an *in camera* review, but that also enables the court to review the agency's claimed redactions without having to pull the contextual information out of the redacted documents for itself." *Id.* at 294.

FDA has failed to provide sufficiently detailed descriptions of the withheld records to permit the Court to make a reasoned decision whether the documents have been legitimately withheld under Exemption 4. Neither FDA's amended *Vaughn* index nor the Engelke Declaration, separately or in conjunction, provide sufficient detail to permit the Court to independently determine whether the withheld information "would 'jeopardize [Juul's] commercial interests or reveal information about [its] ongoing operations.'" *N.Y. Times Co.*, 2021 WL 371784, at *10 (quoting *N.Y. Pub. Int. Rsch. Grp.*, 249 F. Supp. 2d at 333). Juul's internal classification and analysis of customer and non-customer complaints could qualify as commercial information, but the Court is unwilling to decide on this undeveloped record that this information is necessarily commercial under Exemption 4. For instance, if the entirety of Juul's internal classification and analysis consists of tagging a complaint based on its general substance, such as labeling it as a "complaint about exterior product features," this would be far less likely to qualify as commercial information than, for instance, internal Juul analysis focusing on how to alter a product or its marketing strategy in response to the complaint. Juul's attestation that Consumer Experience records reflect Juul's "internal strategy on data collection and response" is far too conclusory to meet FDA's burden to demonstrate the commercial nature of any internal

Juul analysis or communications.[13] *See Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 870 (D.C. Cir. 1980) ("The courts will not speculate as to whether [the] Exemption [] might, under some possible congruence of circumstances not proven or even asserted[,] be properly applied to these documents, nor will [the court] assume that all the necessary conditions are met merely because the agency invokes an exemption.").

Accordingly, although these records may contain information appropriately classified as commercial under Exemption 4, because neither FDA's amended *Vaughn* index nor the Engelke Declaration provides an adequate foundation for Court review, summary judgment for FDA is inappropriate at this time. *See, e.g.*, *Cox v. Dep't of Just.*, No. 17-CV-3329, 2020 WL 7024288, at *23 (E.D.N.Y. Nov. 30, 2020) (denying agency's motion for summary judgment without prejudice where *Vaughn* index was insufficiently detailed).

Further, as discussed below, FDA has not yet had occasion to address the potential of segregating information potentially protectable under Exemption 4 from that which is not protected. As such, FDA must supplement its *Vaughn* index and provide additional detail on these records, should it still seek to withhold them under Exemption 4.[14] *See Seife*, 298 F. Supp. 3d at 630 (instructing that courts should "first offer the agency the opportunity to demonstrate, through detailed affidavits and oral testimony, that the withheld information is clearly exempt

[13] Without additional detail on the nature of any internal Juul classification or analysis of or communication about customer and non-customer complaints, the Court is also skeptical of the extent to which revelation of Juul's "internal strategy on data collection" renders this material commercial. Juul is in the business of manufacturing and selling ENDS products, not collecting data. Nevertheless, the Court is unable to make any determination absent additional detail in FDA's *Vaughn* index and affidavits.

[14] FDA can also provide more detailed affidavits in conjunction with a supplemented *Vaughn* index. *See, e.g.*, *Pub. Citizen v. U.S. Dep't of Health & Hum. Servs.*, 975 F. Supp. 2d 81, 93 (D.D.C. 2013) ("Certainly, the combined use [of] *Vaughn* indices and detailed declarations is an acceptable practice for an agency to justify its application of an exemption.").

and contains no segregable, nonexempt portions" before resorting to *in camera* review (citation omitted)).

B. Privileged or Confidential

As with its analysis of the commercial nature of the withheld records, in assessing whether the records are confidential, the Court must distinguish between the complaints — and Juul's responses to complainants — and any internal Juul analysis and communications. Even if the Court had determined that the complaints are commercial in nature, the Court still would deem FDA's decision to withhold the documents to be overbroad, as the complaints and any response from Juul cannot reasonably be deemed confidential. Although the Court finds that internal Juul communications and analysis of these complaints meet the threshold for confidentiality, and, therefore, to the extent any of this information can properly be deemed commercial, it may be subject to protection under Exemption 4, the fact that some portion of these records may be confidential does not warrant withholding the records in their entirety. *See Besson v. U.S. Dep't of Com.*, 480 F. Supp. 3d 105, 114 (D.D.C. 2020) ("The agency bears the burden of establishing a FOIA exemption's applicability, and by injecting into the record the possibility that some portion of the [document] is public, the agency fails to carry that burden here where it seeks to withhold the [document] in its entirety.").

Prior to 2019, the Second Circuit, as with most courts nationwide, employed a test for "confidentiality" derived from a D.C. Circuit case, *National Parks & Conservation Assoc. v. Morton*, 498 F.2d 765 (D.C. Cir. 1974), pursuant to which commercial information was deemed "confidential for the purposes of Exemption 4 if its disclosure would have the effect either: '(1) of impairing the government's ability to obtain information — necessary information — in the future, or (2) of causing substantial harm to the competitive position of the person from whom the information was obtained.'" *Inner City Press*, 463 F.3d at 244 (quoting *Cont'l Stock*

Transfer & Tr. Co. v. Sec. & Exch. Comm'n, 566 F.2d 373, 375 (2d Cir. 1977) (per curiam) (adopting *National Parks* test)). In 2019, however, the Supreme Court decided *Food Marketing Institute v. Argus Leader Media*, in which it abandoned the *National Parks* test and simplified the confidentiality inquiry. 139 S. Ct. 2356. Pursuant to *Argus Leader*, commercial or financial information provided to the government by a commercial entity qualifies as confidential within the meaning of Exemption 4 at least where it "is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy." *Id.* at 2366. The Supreme Court left open whether the second element had to be met for information to be deemed confidential, as it was unnecessary to the case before it. *Id.* at 2363. While there has been little time in which to interpret the Supreme Court's new standard for confidentiality under Exemption 4, it appears most courts have found it to be significantly less demanding than the prior "substantial competitive harm" test. *See, e.g.*, *Am. Small Bus. League v. U.S. Dep't of Def.*, 411 F. Supp. 3d 824, 832 (N.D. Cal. 2019) ("Under [*Argus Leader*], it appears that defendants need merely invoke the magic words — 'customarily and actually kept confidential' — to prevail. And, unless plaintiff can show that the information is in fact publicly available or possibly point to other competitors who release the information, defendants can readily ward off disclosure.").

1. Complaints and Juul's Responses

FDA asserts that, even though the disputed records "reflect agreements or communications with parties besides Juul, those records and the underlying information remained 'closely held.'" Def. Mem. at 13 (quoting *Argus Leader*, 139 S. Ct. at 2363). FDA further argues that Plaintiffs have failed to identify the existence of these complaints or Juul's responses in any public forums, and any speculation about how the third parties with whom Juul communicates treat these records is inappropriate, especially because of the private nature of emails, phone calls, and other ways in which complaints are submitted to Juul. *See* Def. Reply at

11. In essence, FDA contends that *Argus Leader* instructs courts to focus on how the person who provided the documents to the Government treats them. Here, the FDA argues, Juul is the "person" that provided the records to FDA, and Juul itself treats these records as confidential. That, FDA argues, ends the inquiry. *See id.* at 10–11.

Although FDA's argument is tidy, it is not persuasive. It strains credulity to believe that Juul treats customer and non-customer complaints and Juul's responses as highly protected, confidential information. Although Juul may keep close guard over the summary reports aggregating the complaints as well as any internal Juul analysis and discussion of them, the same cannot be said for the complaints themselves or Juul's responses. FDA is undoubtedly correct that not every instance of third-party access to corporate information extinguishes a claim of confidentiality under Exemption 4. *See id.* But where third-party disclosure has been deemed consistent with a finding that the company treated the information as confidential, there has been some accompanying indication that the company took steps to ensure that the information remained closely held or guarded, or there was at least an implicit understanding that the information would remain limited to a select audience. *See, e.g.*, *Seife*, 2020 WL 5913525, at *5 (finding that certain "'types of limited disclosures,' subject to nondisclosure agreements and 'not made to the general public, do not preclude Exemption 4 protection.'" (quoting *Parker v. Bureau of Land Mgmt.*, 141 F. Supp. 2d 71, 79 (D.D.C. 2001)); *Jud. Watch, Inc. v. U.S. Dep't of Treasury*, 802 F. Supp. 2d 185, 205–06 (D.D.C. 2011) (distinguishing disclosure of information to two employees at Federal Reserve Bank of New York ("FRBNY") from disclosure to general public, as limited disclosure to FRBNY employees was "akin to the type of limited disclosures, such as to suppliers or employees, that do not preclude protection under Exemption 4," and also pointing to the confidentiality legend on the cover letter of the record).

Here, on the other hand, neither FDA nor Juul has pointed to anything that would persuade the Court that the complaints and Juul's responses were kept confidential despite their origination and subsequent dissemination outside of the company. There is no reason to believe that the complainants themselves had an expectation of privacy or confidentiality in submitting their complaints to Juul, nor is there any reason to believe that the complainants did not thereafter publicize their complaints or share their contents more broadly. *See* Pls. Reply at 8 (noting the frequency with which complaints about Juul products were published in public forums). Without any indication from FDA or Juul that complainants submitted their complaints to Juul with an understanding that the complaints were to be kept confidential, the Court finds no reason to stamp them with a label of "confidential information." *Cf. Ctr. for Investigative Reporting v. U.S. Customs & Border Patrol*, 436 F. Supp. 3d 90, 111 (D.D.C. 2019) (rejecting agency's claim of confidentiality for "questions and concerns" submitted to a "general point of contact between the public and [the agency]" where defendants failed to "point to an understanding with the submitters" that their submissions would be kept confidential, especially where "a reasonable submitter may well have assumed that information stored in such a public-facing email account would *not* be confidential by default" (cleaned up)).

FDA has an even weaker claim of confidentiality over Juul's responses. Although FDA has provided virtually no detail on the mode or substance of Juul's responses, there is no indication that Juul responded to complainants only pursuant to a guarantee of confidentiality or secrecy, or that Juul took efforts to ensure complainants would keep Juul's responses private. For all intents and purposes, Juul responded to complainants with full knowledge that its responses could be rebroadcast in all sorts of public forums.[15] The fact that email, "chats,"

[15] FDA argues that, under *Argus Leader*, "information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it." *Argus Leader*, 139 S.

phone calls, and electronic support forms are "non-public transmissions of information," Def. Reply at 11, does not mean that the information is confidential. This is not analogous to situations in which a company imparts information to a third party only after signing a non-disclosure agreement or with an implicit understanding that the recipient of the information will not share it more broadly in a public setting. *See Ctr. for Investigative Reporting v. U.S. Dep't of Labor*, No. 18-CV-2414, 2020 WL 2995209, at *4 (N.D. Cal. June 4, 2020) ("There are no restrictions on further dissemination of the [withheld records] . . . [and, t]herefore, the . . . information is both readily observable by and shared with employees, who have the right to make the information public."); *cf. Argus Leader*, 139 S. Ct. at 2363 ("[I]t is hard to see how information could be deemed confidential if its owner shares it freely."). The record does not reflect that Juul responded to complaints only under strict confidentiality terms or with any understanding that the complainant will keep Juul's response closely held. Simply put, FDA has identified no authority demonstrating that information freely obtained from and disseminated to members of the public can appropriately be classified as "closely held" by the company. Accordingly, neither the complaints themselves nor Juul's responses satisfy the confidentiality prong of Exemption 4's tripartite test. Assuming this information is segregable from any potentially exempt material in these records, pursuant to FOIA, it must be disclosed to Plaintiffs.

2. Internal Juul Information

As to the internal Juul analysis and communications contained with the complaint summary reports and other internal Juul documents, the Court agrees with FDA that, by virtue of

Ct. at 2363. The Court does not understand this statement to mean that a company can disseminate information to members of the public without any assurance or expectation that the information will subsequently be kept confidential and thereafter claim the information is confidential merely by asserting in an affidavit that the company itself still keeps that information closely held. Responding to a third-party complaint with zero assurance of confidentiality by the recipient is, by definition, not treating the information as confidential.

the Engelke Declaration, it has established that those portions of the records are confidential under *Argus Leader*.

a. Customarily and Actually Kept Private or Closely Held

The Engelke Declaration adequately demonstrates that Juul "both customarily and actually treated [the records] as private." *Argus Leader*, 139 S. Ct. at 2366. The Engelke Declaration clearly states that all of the records at issue are "treated as highly confidential within the Company and are stored on secure IT networks that are password-protected and/or encrypted conditions designed to ensure their confidentiality." Engelke Decl, ¶ 22. Similarly, Juul attests that the records "are not customarily shared with individuals who are not employees of the Company, and access is granted to employees only [on] a need-to-know basis."[16] *Id.* ¶ 23. Further, the Engelke Declaration confirms that, to the extent any of the records have been produced in other ongoing legal matters, "[i]n each instance, [Juul] produced the documents strictly on a confidential basis by including appropriate confidentiality language in the cover letter for each production and/or producing the documents under a confidentiality agreement." *Id.* This is the type of third-party disclosure that courts find does not negate a company's treatment of documents as confidential. *Seife*, 2020 WL 5913525, at *5. Finally, Juul asserts that "the various protective measures . . . that [it] takes to protect its trade secrets and confidential commercial information have proven effective in preventing the documents at issue from becoming publicly available." Engelke Decl. ¶ 24.

[16] Although the Court finds that the complaints and Juul's responses themselves are not confidential and are, by nature, shared with those outside of the company, the Court understands Juul's attestation to pertain to the records documenting those complaints, such as the summary reports. As such, the Court does not see any inconsistency in Engelke's statement that Juul treats the records themselves — referring to the complaint summaries and other Juul-produced documents memorializing the complaints and Juul's responses and internal decisions — as confidential by sharing them only with a limited subset of Juul employees. As discussed, however, this does not mean that the entirety of the records' contents may be withheld, but instead necessitates a segregability analysis, redaction of any portion of the records that satisfy Exemption 4's requirements, including confidentiality, and disclosure of the balance.

In the wake of *Argus Leader*, FDA's references to averments from Juul's Chief Quality Officer are sufficient to meet the requirement that the company customarily and actually treats the records as private. *See, e.g.*, *N.Y. Times*, 2021 WL 371784, at *14 ("[T]he [company's] Declarations adequately establish that the Report contains information that [it] 'customarily and actually treated as private.'" (quoting *Argus Leader*, 139 S. Ct. at 2366)); *Seife*, 2020 WL 5913525, at *4–5 (finding records confidential based on company representative's declaration attesting that "such information is subject to strict confidentiality protocols both within and outside [the company]," and giving credence to company attestation that the records had not been publicly released and continued to be maintained internally as confidential). The takeaway from cases in the wake of *Argus Leader*, then, is that a company cannot readily ward off disclosure *simply* by "invok[ing] the magic words — 'customarily and actually kept confidential,'" *Am. Small Bus. League*, 411 F. Supp. 3d at 832, but must instead adequately describe the steps it takes to keep the information at issue confidential. Those steps must seem reasonable to the producing agency (or, if litigation results, the reviewing court), and the company must attest that they have succeeded in maintaining the information's confidentiality. In the face of such an affirmation, unless the plaintiff "can show that the information is in fact publicly available or possibly point to other competitors who release the information," *id.*, the government can avoid disclosure. In this case, Plaintiffs have neither demonstrated that the internal Juul analysis or communications are public nor demonstrated that Juul's competitors, or any companies, readily disclose complaint summary reports and internal analyses of customer complaints.

b. Assurance of Confidentiality

Even if Juul treats the records as private, Plaintiffs contend that, under *Argus Leader*, FDA must also demonstrate that Juul provided the information to the government under an

assurance of privacy. *See* Pls. Mem. at 18, 20 ("The Government also bears the burden of demonstrating that the records withheld were 'both customarily and actually treated as private' and 'provided to the government under an assurance of privacy.'" (quoting *Argus Leader*, 139 S. Ct. at 2366); Pls. Reply at 7 ("'[T]wo conditions' must be satisfied for information to be considered confidential . . . ." (quoting *Argus Leader*, 139 S. Ct. at 2363)). This is a misrepresentation of the Supreme Court's holding in *Argus Leader*; the Supreme Court expressly left open whether the test for confidentiality under Exemption 4 requires the submitter to have provided the information to the government "under an assurance of privacy." *See Argus Leader*, 139 S. Ct. at 2363 ("As it turns out, there's no need to resolve that question in this case . . . ."). In fact, "[a]lthough several district courts have resolved Exemption 4 disputes since [*Argus Leader*], none has held that this potential second prong *must* be met. Put differently, no court has yet held that 'privately held information lose[s] its confidential character for purposes of Exemption 4 if it's communicated to the government without' privacy assurances." *Renewable Fuels Ass'n v. U.S. Env't Prot. Agency*, No. 18-CV-2031, 2021 WL 602913, at *7 (D.D.C. Feb. 16, 2021) (internal citations omitted) (quoting *Argus Leader*, 139 S. Ct. at 2363).

As all courts to address the issue have held, the government's assurance of privacy can be either explicit or implicit, ascertained from the context in which a company provided records to the agency.[17] In this case, the Court does not have to rely on context, because FDA provided

[17] *See, e.g.*, *Seife*, 2020 WL 5913525, at *4 ("'[C]ontext shows' that [the company] supplied the information to the FDA under an implied assurance of confidentiality." (citation omitted)); *Citizens for Resp. & Ethics in Wash. v. U.S. Dep't of Com.*, No. 18-CV-3022, 2020 WL 4732095, at *3 (D.D.C. Aug. 14, 2020) ("Assuming that Exemption 4 can be satisfied here only if [the agency] gave [the company] some assurance of confidential treatment, *Argus Leader*, 139 S. Ct. at 2366, that assurance of confidentiality could have been either express or implied."); *Besson*, 480 F. Supp. 3d at 115 (interpreting *Argus Leader* to endorse the Ninth Circuit's formulation that "Exemption 4 would 'protect information that a private individual wishes to keep confidential for his own purposes, but reveals to the government under the express or implied promise' of confidentiality" (quoting *Argus Leader*, 139 S. Ct. at 2363)).

Juul with an *explicit* assurance of privacy when it collected the records at issue.[18] FDA's April 24, 2018 letter to Juul pursuant to Section 904(b) explicitly stated that, "[c]onsistent with applicable statutes and regulations, the confidentiality of trade secret[s] and confidential commercial information submitted to FDA pursuant to this request will be preserved." Apr. 24, 2018 FDA Letter at 5. As the Court reads it, this is an unambiguous statement by FDA that it would keep confidential Juul's information that qualifies for protection under FOIA Exemption 4. Further, pursuant to section 906(c) of the FDCA, any information obtained by FDA pursuant to a 904(b) request "which is exempt from disclosure under [FOIA Exemption 4] shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other [FDA] officers or employees." 21 U.S.C. § 387f(c). Similarly, FDA's regulations implementing both FOIA and FDCA dictate that "[d]ata and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61 (2020). The Engelke Declaration makes clear that Juul relied on these express assurances of confidentiality when divulging records to FDA in response to the Section 904(b) request. *See* Engelke Decl. ¶ 12.

Plaintiffs nevertheless contend that FDA's assurances of privacy do nothing more than repeat the standard under FOIA Exemption 4. *See* Pls. Mem. at 21–22. According to Plaintiffs, to satisfy the second prong of *Argus Leader*, the Government must provide a "particularized promise of confidentiality, specific to the documents provided." Pls. Reply at 7. Otherwise, under FDA's statutes and regulations, any information divulged by a private company to FDA

[18] The fact that Juul produced the documents with confidentiality markings also suggests that Juul expected that FDA would maintain the confidentiality of the documents and suggests that, beyond the assurances discussed in text, there was an implicit assurance of privacy. *See* Engelke Decl. ¶ 13; *see also id.* ¶¶ 9, 11 (discussing Juul's confidentiality markings and requests for confidentiality to FDA).

would automatically be considered confidential under the "assurance of privacy" inquiry. Plaintiffs, however, cite to no authority to support their position, and the authority of which this Court is aware supports a contrary conclusion. *Cf. N.Y. Times*, 2021 WL 371784, at *14 ("Nor does the release of portions of the Report by [the agency] after determining that withholding was improper under FOIA undermine assurances of confidentiality with respect to commercial information provided by [the company], because the portions of the Report that were released plainly contained no commercial information."); *Friends of Animals v. Bernhardt*, No. 19-CV-1443, 2020 WL 2041337, at *11 (D. Colo. Apr. 24, 2020) ("Defendant's notice assures submitters that their information will not be given, sold, or transferred to third parties except as required by law. This is a direct assurance that their information is private. The fact that the information could be disclosed pursuant to FOIA is true of all information held by the government.").

Plaintiffs' parade-of-horribles argument — if FDA's assurance and its regulations are enough to render the information confidential, all information submitted to FDA would satisfy *Argus Leader*'s potential second prong — is also incorrect. As Plaintiffs see the world, the options are either a detailed representation by the government in advance of receiving requested documents of what it promises to keep private or a blanket assurance that any documents that fall within Exemption 4's protection will be kept confidential; according to Plaintiffs, only the former satisfies the test for confidentiality.[19] But Plaintiffs ignore a third option, in which an agency's record collection is accompanied by an express notice of its intention to *make public*

[19] Plaintiffs ignore the fact that requiring an agency to explicitly detail the specific records it promises to keep confidential before actually collecting those records would impose upon the agency a requirement akin to fortune telling. Without the benefit of knowing what materials a company may turn over, it is sufficient that the agency assure a company generally that it will keep private any information that qualifies as confidential commercial information.

the collected records. In that scenario a company cannot reasonably claim to have received an assurance of privacy, because there would be no expectation that *any* information submitted, regardless of whether it otherwise meets the hallmarks of confidential commercial information under Exemption 4, would be kept private by the agency. *See, e.g.*, *Ctr. for Investigative Reporting*, 2020 WL 2995209, at *5 (finding that, to the extent the "assurance of privacy" requirement exists under *Argus Leader*, the agency could not "satisfy it because [the government] expressly stated in rulemaking in 2016 that it would post the data from the electronic submissions . . . on a publicly accessible Web Site" (cleaned up)); Off. of Info. Pol'y, *Exemption 4 After the Supreme Court's Ruling in* Food Marketing Institute v. Argus Leader Media, U.S. Dep't of Just., https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institute-v-argus-leader-media (last updated Oct. 4, 2019) ("Of course, such notices [on agency websites] or communications [with submitters] could also explicitly notify submitters of the agency's intention to *publicly disseminate* the information. In those situations, the information, when objectively viewed in context, would be deemed to have lost its 'confidential' character under Exemption 4 upon its submission to the government, given that the submitter was on notice that it would be disclosed."); *see also Renewable Fuels Ass'n*, 2021 WL 602913, at *8 (finding that, were it to address the issue, the court "would not read the word 'confidential' to impose a blanket requirement that the government provide an assurance of privacy in every case in which it asserts Exemption 4" and deeming the "better approach" to be that "privately held information is generally confidential absent an express statement by the agency that it would <u>not</u> keep information private, or a clear implication to that effect").

In short, the Court finds that, to the extent required under *Argus Leader*, the FDA has satisfied its burden of showing that the withheld records were provided to the government under an assurance of privacy.

IV. The FOIA Improvement Act of 2016 and the Foreseeable Harm Requirement

In 2016, Congress passed the FOIA Improvement Act of 2016 ("FIA"), Pub. L. No. 114-185, 130 Stat. 538 (2016), which imposes an additional "foreseeable harm" requirement on an agency seeking to withhold records under a FOIA exemption. "The foreseeable harm standard prohibits agencies from withholding information unless (i) 'the agency reasonably foresees that disclosure of the record would harm an interest protected by an exemption,' or (ii) 'disclosure is prohibited by law.'" *N.Y. Times Co.*, 2021 WL 371784, at *6 (quoting *Ctr. for Investigative Reporting*, 436 F. Supp. 3d at 105). Pursuant to this new requirement, agencies must "release a record — even if it falls within a FOIA exemption — if releasing the record would not reasonably harm an exemption-protected interest and if its disclosure is not prohibited by law." *Jud. Watch, Inc. v. U.S. Dep't of Just.*, No. 17-CV-832, 2019 WL 4644029, at *3 (D.D.C. Sept. 24, 2019) (citation omitted). As a court within this district has described it, the FIA "imposes an independent and meaningful requirement on agencies before they may withhold a record under one of FOIA's exemptions." *Nat. Res. Def. Council, Inc. v. U.S. Env't Prot. Agency*, No. 17-CV-5928, 2019 WL 4142725, at *3 (S.D.N.Y. Aug. 30, 2019).

The application of FIA's foreseeable harm requirement to FOIA's Exemption 4 has caused more controversy than perhaps anticipated, as courts have split in ascertaining the "harm" against which Exemption 4 is intended to protect. *See N.Y. Times*, 2021 WL 371784, at *15 n.15 (highlighting the split among district courts and collecting cases on either side). Plaintiffs press the Court to adopt the reasoning of a district court that viewed the foreseeable harm requirement

as requiring an agency to "explain how disclosing, in whole or in part, the specific information withheld under Exemption 4 would . . . caus[e] genuine harm to the submitter's economic or business interests, and thereby dissuad[e] others from submitting similar information to the government." *Ctr. for Investigative Reporting*, 436 F. Supp. 3d at 113 (cleaned up). Pursuant to this interpretation, despite the Supreme Court striking down the "substantial competitive harm" test from *National Parks* in *Argus Leader*, Congress intended FIA's foreseeable harm standard to impose on agencies a requirement to demonstrate some form of competitive harm as a result of disclosure. In response, FDA contends that any test requiring competitive harm, especially in reliance on *National Parks*, finds no support in the statutory text or its legislative history and would be in direct contradiction to the Supreme Court's reasoning in *Argus Leader*. *See* Def. Mem. at 16–17; Def. Reply at 15–16. FDA would instead have the Court side with those district courts that have found the harm protected by Exemption 4 to be confidentiality itself, such that disclosure of any record falling within the scope of Exemption 4 would necessarily satisfy FIA's foreseeable harm requirement. *See Am. Small Bus. League*, 411 F. Supp. 3d at 836 (finding that, as dictated by *Argus Leader*, Exemption 4's "relevant protected interest is that of the information's *confidentiality* — that is, its private nature"); *see also Seife*, 2020 WL 5913525, at *7 (stating that, pursuant to the *American Small Business League* approach, where the information falls within Exemption 4, "the requirement is satisfied because, by definition, disclosure would destroy the confidential nature of the information at issue").

This Court need not jump into this fray just yet. At least with respect to the complaints and Juul's responses, FDA "ha[s] not established that the withheld information falls within the scope of Exemption 4 in the first instance, [and a]s such, [it has], *a fortiori*, failed to satisfy the heightened foreseeable-harm requirement as well." *N.Y. Times*, 2021 WL 371784, at *15

(cleaned up). As for any internal Juul analysis and communications in these records, without adequately detailed descriptions of the information at issue, the Court cannot yet determine whether harm would be foreseeable to an exemption-protected interest as a result of disclosure, regardless of what that interest may be. Should FDA continue to seek to withhold some material in these records, the Court will address the issue on a more developed record.[20]

V. Segregability

Pursuant to FOIA, "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection." 5 U.S.C. § 552(b). Under this provision, "agencies and courts [must] differentiate among the contents of a document rather than . . . treat it as an indivisible 'record' for FOIA purposes." *Fed. Bureau of Investigation v. Abramson*, 456 U.S. 615, 626 (1982). Agencies need not, however, disclose non-exempt information that is "inextricably intertwined" with exempt information. *See Hopkins v. U.S. Dep't of Hous. & Urban Dev.*, 929 F.2d 81, 85 (2d Cir. 1991). Information is deemed inextricably intertwined where "disclosure would compromise the confidentiality of [exempt] information that is entitled to protection." *Id.* (cleaned up). District courts "must make specific findings of segregability regarding the documents to be withheld." *Color of Change v. U.S. Dep't of Homeland Sec.*, 325 F. Supp. 3d 447, 455 (S.D.N.Y. 2018) (quoting *Sussman v. U.S. Marshals Serv.*, 494 F.3d 1106, 1116 (D.C. Cir. 2007)).

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[20] In its opening brief, Plaintiffs also encourage the Court to adopt some form of a public interest exception or balancing test in assessing whether disclosure is required notwithstanding Exemption 4. *See* Pls. Mem. at 22–23. Pursuant to Plaintiffs' proposal, where public health or safety data is at issue, the Court should balance the interests under FOIA and err in favor of disclosure. *See id.* The Court declines to adopt such a balancing test or public interest exception. As a sister court recently stated, "the Court's task is to apply the law and the law is clear: There is no public policy or public health exception that allows for disclosure where, as here, Exemption 4 and the foreseeable harm requirement (to the extent it applies) are met." *Seife*, 2020 WL 5913525, at *7. "The statute as written by Congress sets forth no basis for the exemption Plaintiffs ask the Court to read into it, and if Plaintiffs believe such an exemption would better serve the national interest, they should ask Congress to amend the statute." *Id.* (quoting *Bloomberg, L.P. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 601 F.3d 143, 151 (2d Cir. 2010)) (cleaned up).

In the original Barnes Declaration, FDA affirmed that it had "ensured that any reasonabl[y] segregable non-exempt information within these records was disclosed" and that "[n]o further information from withheld or partially withheld responsive documents could be made without revealing the information exempt from disclosure under 5 U.S.C. § 552(b)." Barnes Decl. ¶¶ 22, 26. At the time of this attestation, however, FDA was advancing the position that the consumer complaint summary reports and other records revealing customer and non-customer complaints were protected in their entirety under Exemption 4. In light of the Court's findings above with respect to Exemption 4, FDA must now conduct a closer review of the complaint summary reports and the other records documenting complaints to assess whether the complaints themselves and Juul's responses can be reasonably segregated and released, to the extent the other information contained in the records is eligible for protection under Exemption 4. To the extent this information is not "inextricably intertwined," at the very least, the consumer and non-consumer complaints and any Juul responses must be disclosed to Plaintiffs.

In sum, FDA has failed to present sufficient evidence to permit the Court to find that it has released all segregable, non-exempt information in the withheld records. As such, FDA's motion for summary judgment is denied. Similarly, while the Court finds that complaints and Juul's responses are not themselves protected under Exemption 4, without an adequate basis on which to determine whether this information is segregable from potentially exempt information, the Court must also deny Plaintiffs' cross-motion for summary judgment.

CONCLUSION

For the foregoing reasons, FDA's motion for summary judgment is DENIED without prejudice and Plaintiffs' cross-motion for summary judgment is DENIED without prejudice. FDA is instructed to submit a revised *Vaughn* index addressing internal Juul classifications, analyses, or communications concerning consumer and non-consumer complaints. FDA must

also supplement the *Vaughn* index entries concerning the records in the Consumer Research and Strategy category. Finally, FDA must submit a segregability analysis concerning any records that contain internal Juul analysis or communication in addition to complaints and Juul's responses to complaints. To the extent FDA seeks to continue withholding the contested records, it must submit a renewed motion for summary judgment along with the above materials not later than **May 17, 2021**. Plaintiffs may submit a renewed cross-motion for summary judgment not later than **June 14, 2021**. The Court also encourages the parties to meet-and-confer in light of this opinion to determine whether further motion practice can be obviated by a mutually agreeable production of records.

The Clerk of Court is respectfully requested to terminate the open motions at Dkt. 19 and Dkt. 25.

SO ORDERED.

Date: March 29, 2021
New York, New York

VALERIE CAPRONI
United States District Judge